Complete Summary

GUIDELINE TITLE

Recommendations for influenza immunization of children.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for influenza immunization of children. Pediatrics 2004 May;113(5):1441-7. PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Influenza

GUIDELINE CATEGORY

Prevention
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Dermatology
Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Otolaryngology
Pediatrics

Preventive Medicine
Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To update recommendations for routine use of influenza vaccine in children and to review the indications for use of trivalent inactivated influenza vaccine and live-attenuated influenza vaccine

TARGET POPULATION

Healthy children between 6 and 24 months of age, children and adolescents at high risk for hospitalization or complications due to influenza, women in their second or third trimester of pregnancy during influenza season, and persons in close contact with high-risk children such as:

- All health care personnel in contact with pediatric patients in hospital and outpatient settings
- Household contacts and out-of-home caregivers of high-risk individuals of any age
- Children who are members of households with high-risk adults, including those with symptomatic human immunodeficiency virus (HIV) infection
- Home caregivers for children and adolescents in high-risk groups

INTERVENTIONS AND PRACTICES CONSIDERED

1. Trivalent inactivated influenza vaccine (TIV) (Fluzone, Fluvirin)
2. Live-attenuated influenza vaccine (LAIV) (FluMist)

MAJOR OUTCOMES CONSIDERED

- Vaccine coverage
- Incidence of influenza and influenza-associated complications
- Influenza-associated hospitalization rates
- Safety and efficacy of influenza vaccines
- Costs of influenza immunizations
- Adverse effects of influenza vaccine

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

US Preventive Services Task Force System of Quality of Scientific Evidence

I: Evidence obtained from at least 1 properly designed, randomized controlled trial

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferentially from more than 1 center or group

II-3: Evidence obtained from multiple time series with or without the intervention, or dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s)

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Costs of Trivalent Inactivated Influenza Vaccine (TIV) Immunization

Whether universal immunization of young children would result in a net cost or a net savings to society depends on the influenza attack rate, the rates of health outcomes (i.e., outpatient visits, hospitalizations, and deaths), and the cost of immunization. The attack rate and rates of health outcomes can vary considerably from year to year, and regional variation in both of these factors is possible within a given season. These variations make it impossible to generate a single precise estimate of the cost-effectiveness or the cost-benefit of universal immunization of children.

The total cost of immunizing a single child includes direct and indirect costs. The direct costs include supplies (e.g., syringe, vaccine), personnel, and administrative expenses. Indirect costs can be a significant component of the total cost of immunization. One of the most important factors is the time lost from work by caregivers of children to be immunized. Three studies have suggested that universal childhood immunization may be cost saving if immunizations could be performed in a group-based setting, such as an after-hours or weekend immunization clinic that would not require a parent to miss work. A subcommittee of the Advisory Committee on Immunization Practices, after a review of the major economic studies of influenza immunization, concluded that universal influenza immunization of young children may generate savings, from a societal perspective, if the total costs of immunization are less than $30 per child immunized.

Public and private insurers should be responsible for payment of costs for the influenza vaccine for children. Transferring financial responsibility to intermediate risk-bearing entities, such as independent practice associations or other physician groups, individual physicians, or hospitals will result in children not being immunized and should not be allowed. Physicians incur significant administrative expenses associated with ensuring that children are fully immunized in a timely fashion, including explaining the benefits and risks of immunization to parents; ordering, purchasing, storing, and administering vaccines; recording immunizations in patients´ charts; tracking immunization schedules and notifying patients; and other activities. Therefore, they should receive reimbursement for the expenses associated with these tasks for each vaccine administration.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the American Academy of Pediatrics (AAP): In October 2004, AAP released additional information for clinicians regarding the prioritization of remaining influenza vaccine supplies during the 2004 shortage. This information is available from the AAP Web site.

Definitions for the strength of the evidence (I-III) are given at the end of the "Major Recommendations" field.

Trivalent Inactivated Influenza Vaccine (TIV) Indications

1. Health care professionals should be diligent with their efforts, through tracking and reminder systems, to ensure that children traditionally considered at high risk of severe disease and complications from influenza infection receive annual influenza immunization. High-risk children and adolescents who should receive priority for influenza immunization are those with the following (evidence grade II-3):
    - Asthma or other chronic pulmonary diseases, such as cystic fibrosis
    - Hemodynamically significant cardiac disease
    - Immunosuppressive disorders or therapy
    - Human immunodeficiency virus (HIV) infection
    - Sickle cell anemia and other hemoglobinopathies
    - Diseases requiring long-term aspirin therapy, such as rheumatoid arthritis or Kawasaki disease
    - Chronic renal dysfunction
    - Chronic metabolic disease, such as diabetes mellitus

    Other individuals who should receive priority for influenza immunization include:

    - Women who will be in their second or third trimester of pregnancy during influenza season (evidence grade II-3)
    - Persons who are in close contact with high-risk children, including (evidence grade II-3):
        - All health care professionals in contact with pediatric patients in hospital and outpatient settings
        - Household contacts and out-of-home caregivers of high-risk individuals of any age
2. Young, healthy children are at high risk of hospitalization for influenza infection; therefore, the American Academy of Pediatrics recommends influenza immunization of healthy children between 6 and 24 months of age (evidence grade II-3). This applies to any child who will be 6 through 23 months of age at any time during the influenza season, which extends from the beginning of October through March. Children should not be immunized before they reach 6 months of age. Influenza immunization of household contacts and out-of- home caregivers of children younger than 24 months of age also is recommended (evidence grade III). Immunization of close contacts of children younger than 6 months may be particularly important, because these infants will not be immunized.
3. Trivalent inactivated influenza vaccine (TIV) may be given to any person older than 6 months of age who (or whose parent) wishes to prevent influenza.

Persons who should not receive TIV include:

- Individuals who have had anaphylactic reaction to chicken or egg proteins or any other component of the vaccine, such as thimerosal

Live-Attenuated Influenza Vaccine (LAIV) Indications

LAIV is indicated for healthy individuals 5 years to 49 years of age who want to be protected against influenza. TIV is preferred for close contacts of immunosuppressed individuals.

Persons should not receive LAIV if any of the following criteria are present:

- Age less than 5 years
- History of anaphylactic reaction to egg or chicken protein
- Receiving salicylates
- Known or suspected immune deficiency
- History of Guillain-Barré Syndrome (GBS)
- Reactive airway disease or asthma
- Other conditions traditionally considered high risk for severe influenza (chronic pulmonary disorders or cardiac disorders, pregnancy, chronic metabolic disease, renal dysfunction, hemoglobinopathies, immune deficiency, or immunosuppressive therapy)

US Preventive Services Task Force Rating System of Quality of Scientific Evidence

I: Evidence obtained from at least 1 properly designed, randomized controlled trial

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II-3: Evidence obtained from multiple time series with or without the intervention, or dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s)

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (See the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate and timely use of trivalent inactivated influenza vaccine (TIV) and live-attenuated influenza vaccine (LAIV)
- Decreased influenza-associated hospitalization rates for pediatric patients
- Decreased incidence of influenza and influenza-associated complications among pediatric patients

POTENTIAL HARMS

Trivalent Inactivated Influenza Vaccine (TIV)

- The most common adverse effects associated with TIV are soreness at the injection site and fever. Mild systemic symptoms, such as nausea, lethargy, headache, muscle aches, and chills, are also reported.
- During the "swine flu" vaccine program in 1976, an increase in the number of cases of Guillain-Barré syndrome (GBS) was reported in adults within 10 weeks after immunization. Further investigations have revealed that there may be a slight increase in the risk of GBS (approximately 1 additional case of GBS per 1 million vaccine recipients) among adults after influenza immunization, at least in some years.
- A newly described syndrome, oculorespiratory syndrome, was described during 2000–2001 among 3.4% of adult recipients of an influenza vaccine distributed in Canada by Shire Biologics (Fluviral S/F).
- Studies of the safety of TIV immunization of children and adults with human immunodeficiency virus (HIV) infection have yielded conflicting results. Some have demonstrated a transient (2- to 8-week) increase in HIV-1 replication and/or a decrease in CD4+ T-lymphocyte cell counts, but others have shown no significant effect. Most experts believe that the benefits of immunization with TIV far outweigh the risks in children with HIV infection.
- Urticarial reactions to TIV have been reported.

Live-Attenuated Influenza Vaccine (LAIV)

In an unplanned retrospective analysis, a statistically significant increase in asthma or reactive airway disease was observed for children 12 to 59 months of age after dose 1 (relative risk: 3.53; 90% confidence interval [CI]: 1.1, 15.7). Because of this finding, FluMist is currently not licensed by the Food and Drug Administration for children younger than 60 months of age.

CONTRAINDICATIONS

CONTRAINDICATIONS

Trivalent Inactivated Influenza Vaccine (TIV)

- Persons who should not receive TIV include individuals who have had anaphylactic reaction to egg proteins or any other component of the vaccine, such as thimerosal.
- History of Guillain-Barré syndrome is considered a relative contraindication to immunization with TIV.

Live-Attenuated Influenza Vaccine (LAIV)

Persons should not receive LAIV if any of the following criteria are present:

- Age less than 5 years
- History of anaphylactic reaction to egg protein
- Receiving salicylates
- Known or suspected immune deficiency
- History of Guillain-Barré syndrome (GBS)
- Reactive airway disease or asthma
- Other conditions traditionally considered high risk for severe influenza (chronic pulmonary disorders or cardiac disorders, pregnancy, chronic metabolic disease, renal dysfunction, hemoglobinopathies, immune deficiency, or immunosuppressive therapy)

QUALIFYING STATEMENTS

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The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for influenza immunization of children. Pediatrics 2004 May;113(5):1441-7. PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Dec (revised 2004)

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Committee on Infectious Diseases

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Reduction of the influenza burden in children. Pediatrics 2002 Dec;110(6):1246-52.

American Academy of Pediatrics (AAP) Policies are reviewed every 3 years by the authoring body, at which time a recommendation is made that the policy be retired, revised, or reaffirmed without change. All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Pediatrics (AAP) Policy Web site.

Print copies: Available from AAP, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Flu vaccine supply halved. Elk Grove Village (IL): American Academy of Pediatrics; 2004 Oct. 1 p.

Electronic copies: Available from the AAP Web site.

Print copies: Available from AAP, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 15, 2003. The information was verified by the guideline developer on June 9, 2003. This summary was updated by ECRI on June 8, 2004. The updated information was verified by the guideline developer on July 6, 2004. This summary was updated by ECRI on October 20, 2004 after the Centers for Disease Control and Prevention (CDC) issued interim recommendations in response to the shortage of influenza vaccine.

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